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K 961704

XIII. SAFE MEDICAL DEVICES ACT SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)

- I. Classification Name and Number: Endodontic Splint (76ELS)
- II. Common/Usual Name: Dental Anchor Post, titanium or titanium alloy.
- III. Proprietary Name: Dentatus MTI™ Anchor Post.
- IV. Classification: These devices were classified by the Dental Devices Panel (Title 21 CFR 872.3890.
- V. Brief Literature Review: Endodontic splints made of titanium or titanium alloy have been proved safe and effective through the years. A Medline literature search under endodontic-splint, or anchor, produced 32 pertinent articles. These were reviewed and summarized showing that this is not an active research field. The literature summarized showed that the endodontic splint is an old, well-known dental device with a broad area of safe and effective uses.
- VI. Substantial Equivalence: The Dentatus products are substantially equivalent to the pre-amendment devices classified under CFR 872.3890, to many endodontic splints manufactured before May 28, 1976, and to devices cleared by the 510(k) process such as the Biotechnics, Inc., "Radicular Bio-Ceramic Pin," cleared under K-834363 and assigned the code ELS.
- VII. Technology: These devices are manufactured from the titanium materials proved effective by the above summarized years of clinical usage, may be sterilized by the standard methods including radiation or ethylene oxide and autoclaving in the dental office, and are constructed according to methods in the cited substantially equivalent products. Thus, they involve no new types of technology and no new technological questions.
- VIII. Decision Tree: The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" from ODE Guidance Memo #86-3 was followed.

End of Summary